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Pesticide Registration Standard
3-(Methylsuflonyl -o- (Methylamino) Carbonyl Oxime-2-Butanone (Butoxicarboxime)

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Butoxicarboxime

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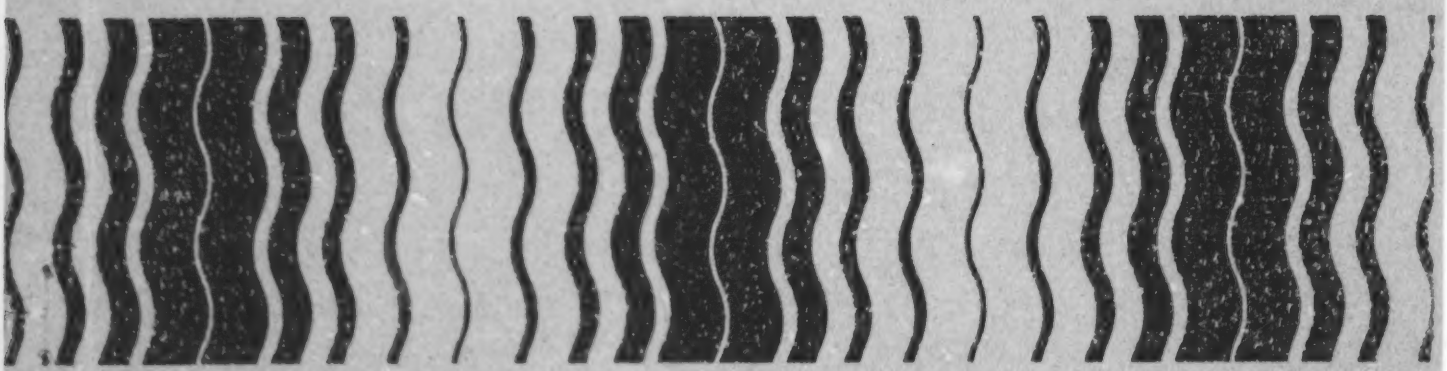

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BUTOXICARBOXIME

Pesticide Registration Standard

Denise Keehner - Project Manager (SPRD)
Michael McCommas - Project Manager (SPRD)

Jay Ellenberger - Product Manager (RD)
Dennis Edwards - Product Manager (RD)

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Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

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A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

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Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination

is stated in the second chapter.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific , i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertains to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to

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characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products are also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed guidelines,43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. "Exclusive Use" and "Data Compensation" Under FIFRA Section 3(C)(1)(D)

FIFRA section 3(C)(1)(D)(i) provides special "exclusive use" protection for certain data concerning any pesticide product first registered after September 30, 1978, that contains an active ingredient not found in any previously

registered product. (Plant-Pin^{R}, with its new active ingredient butoxicarboxime, is such as product.)

The statute provides that data submitted to support the original registration of such a product may not be considered by EPA to support the registration of another firm's product unless the original data submitter has consented in writing. This period of "exclusive use" lasts for 10 years after the initial registration. Wacker Chemie's registration for its Plant-Pin^{R} product was issued on May 28, 1979. The Chapter III data charts contained within this standard indicate those data which are subject to this "exclusive use" provision.

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, and amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be <u>required</u> to offer to pay for "product specific"

data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite those data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will

issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

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CHAPTER II

AGENCY POSITION ON BUTOXICARBOXIME

Introduction

This chapter describes in detail the Agency's regulatory position on products which contain butoxicarboxime as the sole active ingredient. The regulatory position adopted by the Agency incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of products containing butoxicarboxime based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency's determination and the rationale for its determination are presented below.

In addition to this decision, standards of product composition, acute toxicity, and use are established. The rationale for establishing a particular standard follows the presentation of the standard. Regulatory actions such as requiring the addition of a bitter tasting ingredient to decrease the possibility of children ingesting fatal quantities of butoxicarboxime are prescribed, and any additional data to support the registration are requested. The basis for any regulatory action can be found by first reading the rationale for the action, which follows the chosen option. Further information, on the scientific basis for an action, can be found by reading the various disciplinary chapters which present summaries of available scientific data on the safety of butoxicarboxime.

The data base on butoxicarboxime was complete, to satisfy Agency requirements for the registration of end-use butoxicarboxime products for indoor, non-food uses. Certain categories of data were waived because of the nature of the formulation (butoxicarboxime embedded between two cardboard strips). Agency requirements for the submission of efficacy data were also waived, because butoxicarboxime is not registered for any public health uses. The currently registered butoxicarboxime product meets all standards and conditions for reregistration.

Proposed manufacturing-use products, intended for reformulation into insecticidal "pins", are acceptable under this Standard for indoor, non food-use applications.

Description of Chemical

Butoxicarboxime is a plant systemic insecticide used for the control of aphids and two-spotted spider mites on potted ornamental plants. Butoxicarboxime is the common name for 3-(methylsulfonyl)-O-[(methylamino) carbonyl] oxime-2-butanone. The Chemical Abstracts Registry (CAS) number for butoxicarboxime is 39196-18-4 and the EPA Shaughnessy Number is 113001.

There is no currently registered manufacturing-use product. The sole registered product (registered on May 28, 1979) is an end-use product containing 9.8% butoxicarboxime. It is marketed under the trade name Plant Pin®, and is formulated as a 8 mm X 40 mm cardboard "pin". The active ingredient is sandwiched between two cardboard strips.

Regulatory Position

Butoxicarboxime (3-(methylsulfonyl)-O-[(methylamino) carbonyl] oxime-2-butanone), as described in this Standard, may be registered for sale, distribution, reformulation and use in the United States. In preparing this Standard, the Agency has considered the scientific data obtained from the open literature through April 1981, and data submitted by the registrant up through the date of publication of the Standard. Based on a review of these data the Agency finds that butoxicarboxime has neither met nor exceeded any of the risk criteria found in section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. Therefore, the Agency has determined that butoxicarboxime does not cause unreasonable adverse effects to either man or the environment when used in accordance with prescribed label directions and precautions.

Currently registered end-use products containing butoxicarboxime as the sole active ingredient may be reregistered under this Standard. New end-use products may be registered under this Standard, provided the proposed products meet acceptable standards of product composition, use and toxicity as described below.

Proposed manufacturing-use products may also be registered under this Standard, provided the proposed product(s) meets acceptable standards of product composition, toxicity, and use.

Regulatory Rationale

Butoxicarboxime is currently registered for indoor, domestic, non-food uses. The only available end-use product is a 8 mm X 40 mm long "pin" containing 9.8% active ingredient sandwiched between two cardboard strips. The "pin" is inserted completely into the soil of houseplants to systemically control aphids and spider mites.

This chemical is not currently registered for outdoor or food uses. The formulation type and method of application are not expected to result in chronic exposure to man or the environment. Therefore, only acute toxicity, teratogenicity and product chemistry data are required to support the current registration.

Proposed manufacturing-use products, intended for reformulation into indoor, non food-use insecticidal "pins" are acceptable under this Standard. The existing data base supports the registration of such a product, provided that the proposed product has been determined to be the same as the technical grade

of the active ingredient. Additional acute toxicity data and product chemistry information on the proposed manufacturing-use product would be required if the Agency determines that the proposed manufacturing-use product is not the same as the technical grade of the active ingredient.

The Agency has determined that additional "generic" toxicology data, and additional product chemistry data would be needed (on the technical grade of the active ingredient) for the registration of a manufacturing-use product intended for reformulation into an end-use product with a higher potential for significant exposure, ie. a liquid or spray formulations.

The Agency has completed a thorough review of the data on the safety of butocarboxime and butoxicarboxime, and has concluded that the use of butoxicarboxime will not result in unreasonable adverse effects to man or the environment. Available data included acute dermal, primary eye irritation, mutagenicity, teratogenicity, oncogenicity and reproduction testing of technical grade butocarboxime; acute inhalation testing of a 50% emulsifiable concentrate containing butocarboxime; acute oral, neurotoxicity and 90-day subchronic testing of technical grade butoxicarboxime; and acute oral, primary eye irritation and 28-day subchronic testing of formulated butoxicarboxime. Butoxicarboxime, the active ingredient in Plant Pin®, is a derivative of butocarboxime. In plants and animals, butocarboxime oxidizes to butoxicarboxime. Thus, available acute and chronic testing of butocarboxime will fulfill Agency testing requirements for testing of technical grade butoxicarboxime.

The Agency's only concern regarding the safety of end-use butoxicarboxime products is that following application, young children may be at risk through accidental ingestion. Following parental insertion of the "pins" into the soil, young children may be tempted to retrieve the "pins" from the soil of houseplants. For this reason, the Agency will not consider the registration of end-use products for domestic use which fall into category I for acute oral toxicity under this Standard (an amendment is required). Registrants of end-use products have the option of limiting the acute oral toxicity to categories III and IV, or of adding a proven child repellent ingredient to products which fall into category II for acute oral toxicity. These additives, designed to make the "pin" less palatable, will prevent the ingestion of fatal quantities of butoxicarboxime by children and pets.

Criteria for Registration Under the Standard

To be subject to this Standard, butoxicarboxime products must:

- contain butoxicarboxime as the sole active ingredient;
- be within any established standards of product composition;
- be within acceptable acute toxicity limits;
- be labeled for acceptable end-uses; and
- bear required labeling.

The applicant for registration or reregistration of products under this Standard must comply with all terms and conditions described in this Standard including a commitment to fill any data gaps in accordance with the time schedule specified by the Agency, and when applicable offer to pay compensation to the extent required under Section 3(c)(1)(D) of FIFRA, as amended, 7 U.S.C. 136(c)(1)(D). As discussed in Chapter I, applicants for registration under this Standard must contact the Agency for specific instructions, including updated information on data and compensation requirements.

Because butoxicarboxime was initially registered as a new active ingredient after September 30, 1978, the sole registrant (Wacker Chemie) is entitled to exclusive use of data generated for the registration of this product (FIFRA s. 3(c)(1)(D)(i)). These data are entitled to a 10-year period of protection, beginning on May 28, 1979. During this period, the Administrator may not grant any application for registration which relies on the protected data unless the original submitter of the data (Wacker Chemie in this case) has consented in writing.

A. Manufacturing-use Butoxicarboxime

1. Acceptable Ranges and Limits

a. Product Composition Standard

There is no currently registered manufacturing-use butoxicarboxime product. Thus, there are no limits on product composition at this time. Data are required, however, on the physical and chemical properties of technical grade butoxicarboxime to support the registration of end-use products.

Proposed manufacturing-use butoxicarboxime products are acceptable under this Standard, with appropriate certification of limits. The Agency must be supplied with product composition, and physical/chemical property data on proposed manufacturing-use products which are not the same as the technical grade of the active ingredient.

b. Acute Toxicity Limits

The Agency will consider registration of proposed manufacturing-use butoxicarboxime products which have established acute toxicity I-IV ratings for each of the following effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation

c. Use Patterns

To be covered under this Standard, proposed manufacturing-use butoxicarboxime products must be labeled for formulation into end-use pesticides intended for indoor, non food-use applications.

The "generic" toxicology data base supports the registration of any proposed manufacturing-use product which is intended for reformulation into a particular type of end-use product, ie. "pins" for insertion into soil. Additional toxicology and product chemistry data on the technical grade of the active ingredient may be required for the registration of a proposed manufacturing-use product intended for reformulation into products which present a higher potential for significant exposure.

Butoxicarboxime is currently registered for use only on indoor, ornamental plants in the domestic (household) setting.

The Agency will consider a non-domestic, indoor use (ie. greenhouse use) under this Standard provided any additional data required to support the non-domestic

use (additional data on physical/chemical properties) are submitted, found to be adequate, and do not indicate that the use pattern will result in any unreasonable adverse effects to applicators.

This Standard must be amended to register butoxicarboxime for outdoor and/or food-use applications. Additional product safety data in the areas of environmental fate, ecological effects, toxicology, and residue chemistry are needed for the registration of butoxicarboxime for outdoor and/or food uses. Refer to process for submission of amendments on page 1-6.

2. Required Labeling

All proposed manufacturing-use products must bear appropriate labeling as specified in 40 CFR 162.10.

3. Tolerance Reassessment

Current use patterns do not require tolerances or exemptions from tolerances.

B. End-Use Butoxicarboxime

1. Acceptable Ranges and Limits

a. Product Composition Standard

Currently registered butoxicarboxime is formulated as a 8 mm X 40 mm cardboard "pin", containing 9.8% active ingredient imbedded between two cardboard strips. End-use butoxicarboxime products containing any percentage of active ingredient are acceptable (with appropriate certification of limits) under this Standard.

The Agency will allow any percentage of active ingredient because acute toxicity testing of technical grade butoxicarboxime (containing 94-96% butoxicarboxime) indicates no greater than moderate acute toxicity.

b. Acute Toxicity Limits

Because of the limited potential for human exposure or adverse ecological effects through the indoor, domestic use of products containing butoxicarboxime, the Agency will consider end-use products in the following toxicity categories:

	I	II	III	IV
Acute oral toxicity	Amendment	Yes*	Yes	Yes
Acute dermal toxicity	Yes	Yes	Yes	Yes
Acute inhalation toxicity	Yes	Yes	Yes	Yes
Primary eye irritation	Yes	Yes	Yes	Yes
Primary dermal irritation	Yes	Yes	Yes	Yes

End-use butoxicarboxime products formulated and applied in a substantially similar manner to the currently registered product (i.e. active ingredient imbedded in non-toxic material and pushed into the soil of ornamental plants) are acceptable with category I-IV ratings for acute dermal toxicity, acute inhalation toxicity and primary eye and primary dermal irritation. The Agency has determined that categories I-IV are acceptable for (general) domestic use because the formulation type and method of use can be reasonably expected to eliminate the routes of exposure.

* End-use butoxicarboxime products with category III-IV ratings for acute oral toxicity are acceptable for domestic use under this Standard. The Agency has determined that products with an acute oral toxicity rating in category II are also acceptable for registration under this Standard provided registrants add a proven child repellent ingredient. This option has been selected because the Agency is concerned about the possibility of young children ingesting butoxicarboxime following application.

c. Use Patterns and Application Methods

To be registered under this Standard, butoxicarboxime products may only be used indoors, on non food-use crops.

Additional Uses

Butoxicarboxime is currently registered for indoor, domestic, non-food uses. Products can be registered for non-domestic use under this Standard provided any additional required data (physical/chemical properties of technical grade butoxicarboxime) are submitted and found to be adequate.

Butoxicarboxime products cannot be registered for outdoor uses or for food-uses under this Standard because of the lack of environmental fate, ecological effects data and established tolerances. An amendment to this Standard is required for the registration of these uses.

2. Required Labeling

All end-use products containing butoxicarboxime must display appropriate labeling as specified in 40 CFR 162.10. The guidance package that accompanies this Standard contains specific information regarding label requirements.

CHAPTER III

DATA REQUIREMENTS AND DATA GAPS

A. Generic Data Requirements and Data Gaps

Table A, entitled: "GENERIC DATA REQUIREMENTS: BUTOXICARBOXIME", includes those data that pertain to the properties or effects of butoxicarboxime as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all products containing butoxicarboxime. Providing data to fill indicated gaps in the data base is the primary responsibility of the manufacturing-use product registrant(s). Because there is no currently registered manufacturing-use butoxicarboxime product, any needed data must be provided by the registrant of the sole registered end-use product to obtain reregistration.

Wacker Chemie, the sole registrant of butoxicarboxime products, is entitled to exclusive use of these data for a ten year period, starting on September 30, 1978 (FIFRA s. 3(c)(1)(D)(i)). These data may not be used to support any application for registration without the written permission of Wacker Chemie.

Product Chemistry Data

Certain data on the physical/chemical properties of technical grade butoxicarboxime are required for the registration of any product containing butoxicarboxime as the sole active ingredient.

Toxicology Data

The potential for chronic exposure to butoxicarboxime, or to residues of butoxicarboxime is low because of the use pattern (non-food use), and the unique type of formulation and method of application. The Agency has determined that acute oral toxicity testing, acute dermal toxicity testing, acute inhalation toxicity testing, acute delayed neurotoxicity testing, and teratogenicity testing (in one species) on the technical grade of the active ingredient are the only toxicology data requirements for the registration of butoxicarboxime for domestic, indoor, non-food uses.

Environmental Fate, Residue Chemistry, and Ecological Effects

The currently registered end-use butoxicarboxime product is not registered for outdoor or food uses. Environmental fate data, residue chemistry data, and ecological effects data are not required to support current uses.

B. Product-Specific Data Requirements and Data Gaps: Manufacturing-use Products

Table B, entitled: "PRODUCT-SPECIFIC DATA REQUIREMENTS: MANUFACTURING-USE BUTOXICARBOXIME", includes those data which are required for the registration of a proposed manufacturing-use product under this Standard (for domestic/non domestic indoor non-food uses).

Product Chemistry Data

Certain data on the composition aand physical/chemical properties of any proposed manufacturing-use product are required if the proposed product is not equivalent to the technical grade of the active ingredient.

Toxicology Data

Acute toxicity data on the proposed manufacturing-use product may be required if the proposed manufacturing-use product is not toxicologically equivalent to the technical grade of the active ingredient.

C. Product Specific Data Requirements and Data Gaps: End-Use Products

Table C, entitled: "PRODUCT SPECIFIC DATA REQUIREMENTS: END-USE BUTOXICARBOXIME" includes those data that relate only to the properties or effects of an end-use product with a specific composition. Thus, these data are required to support the registration(s) of each end-use product with a specific composition. Providing data to fill these requirements is the reponsibility of each applicant for the registration of an end-use product.

Applicants for the registration of new end-use butoxicarboxime products must submit all product-specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product-specific data.

Product Chemistry Data

Because end-use butoxicarboxime is formulated as "pin" for insertion into soil, data on the physical/chemical properties of technical grade butoxicarboxime will provide sufficient information for the registration of the sole end-use product for domestic use. Additional data on the physical/chemical properties of technical grade butoxicarboxime are required for the registration of this active ingredient for non domestic (greenhouse) uses.

Toxicology Data

The only data required on the currently registered end-use product is acute oral toxicity testing, and primary eye irritation testing. These data are required because of the potential for accidental ingestion of end-use butoxicarboxime by young children following "application". Eye irritation testing is required because of the possibility of homeowners transferring residues of butoxicarboxime into the eyes following application. Data provided on the acute dermal toxicity of technical grade butoxicarboxime fulfill Agency requirements for this category of testing.

Although acute inhalation toxicity testing of technical grade butoxicarboxime was available, these data are not required for the registration of this end-use product.

Primary dermal irritation testing was not available for either technical grade butoxicarboxime or the currently registered end-use product. These data are not required.

TABLE-A: BUTOXICARBOXIME
GENERIC DATA REQUIREMENTS: PRODUCT CHEMISTRY

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? Month and Year Data Due.
PRODUCT CHEMISTRY						
163.61-3(b)	Identification	Yes	Tech. Grade*	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(1)	Color	Yes	Tech. Grade	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(2)	Odor	Yes	Tech. Grade	Yes	Wacker Chemie, 1973, GS0077031	No
163.61-8(3)	Melting Point	Yes	Tech. Grade	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(4)	Solubility	Yes	Tech. Grade	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(5)	Stability	Yes	Tech. Grade	Yes	Braunling, 1976, GS0077006 Braunling, 1974, GS007705	No
163.61-8(7)	Physical State	Yes	Tech. Grade	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(10)	Vapor Pressure	Yes	Tech. Grade	Yes	Wacker Chemie, 1974, GS0077031	No

Data Requirements Current as of August 1981. Refer to Guidance Package for any new Requirements after this date.

* Technical Grade Butoxicarboxime

TABLE-A (con): BUTOXICARBOXIME
GENERIC DATA REQUIREMENTS: TOXICOLOGY

Guideline Citation	Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? Month and Year Data Due.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	Technical*	Yes	Zipf, 1971, GS0077045 Zipf, 1971, GS0077043	No
163.81-2	Acute Dermal Toxicity	Yes	Technical	Yes	Huismans and Williams, 1972, GS0077010	No
163.81-3	Acute Inhalation	Yes	Technical	Yes	Kruysse, 1973, GS0077012	No
163.81-7	Acute Delayed Neurotoxicity	Yes	Technical	Yes	Ross et al., 1977, GS0077018	No
163.82-1	Subchronic Oral Toxicity	No	Technical	Yes[1]	[Til, 1973, GS0077024] [Sinkeldam, 1974, GS0077019]	No
163.82-2	Subchronic (21-day) Dermal Toxicity	No	--------	------	----------	-----
163.83-1	Chronic Feeding	No	Technical	Partial[1]	[Til et al., 1977, GS0077023]	No
163.83-2	Oncogenicity	No	Technical	Partial[1]	[Til et al., 1977, GS0077023]	No
163.83-3	Teratogenicity	Yes	Technical	Yes	Koeter, 1975, GS0077011	No[2]
163.83-4	Reproduction	No	Technical	Yes[1]	[Til et al., 1977, GS0077025]	No
163.84-1-4	Mutagenicity	No	Technical	Partial[1]	[Willems, 1977, GS0077042]	No
163.85-1	Metabolism	No	---------	------	----------	----

Data Requirements Current as of August, 1981. Refer to Guidance Package for any new Requirements after this date.

* Technical Grade Butoxicarboxime or technical grade butocarboxime.
[ ]- Available data on butocarboxime.

1- Although data are not required on this topic for the current registration, some data on this topic were available for review. Additional testing is not required.

2- Because the results of the submitted study indicates no adverse effects, and because significant exposure is not anticipated additional testing is not required.

TABLE-B: BUTOXICARBOXIME
PRODUCT-SPECIFIC DATA REQUIREMENTS: PROPOSED MANUFACTURING-USE PRODUCTS
PRODUCT CHEMISTRY

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)? Month and year data due.
PRODUCT CHEMISTRY						
163.61-3	Prod. Identity and Disclosure of Ingredients	Yes	Each Product[1]		Wacker Chemie, 1974, GS0077031	
163.61-4	Description of Manufacturing Process	Yes	Each Product[1]		Mueller et al., 1970, GS0077015 Wacker Chemie, 1974, GS0077038	
163.61-5	Disc. of Formation of Uhint. Ingredients	Yes	Each Product[1]		Wacker Chemie, 1974, GS0077031	
163.61-6	Declaration of Ingredient Limits	Yes	Each Product[1]		Wacker Chemie, 1974, GS0077031	
163.61-7	Product Analyt. Methods and Data	Yes	Each Product[1]	Partial: Need Data	Wacker Chemie, 1976, GS007738 Braunling, 1973, GS0077002	Yes[2]
163.61-8(7)	Physical State	Yes	Each Product[1]			
163.61-8(8)	Density or Specific Gravity	No[3]	Each Product[1]			
163.61-8(10)	Vapor Pressure	No[3]	Each Product[1]			
163.61-8(11)	pH	No[3]	Each Product[1]			
163.61-8(12)	Storage Stab.	No[3]	Each Product[1]			
163.61-8(13)	Flammability		Each Product[1]			
163.61-8(14)	Oxidizing or Reducing Action		Each Product[1]			
163.61-8(15)	Explosiveness	No[3]	Each Product[1]			
163.61-8(16)	Miscibility	No[3]	Each Product[1]			
163.61-8(17)	Viscosity	No[3]	Each Product[1]			
163.61-8(18)	Corrosion Characteristics	No[3]	Each Product[1]			

Data requirements are current as of August, 1981. Refer to Guidance Package for new requirements after this date.

1- There is no registered manufacturing-use product, information would be needed on proposed manufacturing-use products, if they are not equivalent to the technical grade of the active ingredient.

2- Data have been submitted on the technical grade of the active. Data on the MUP must be submitted at the time that application for registration is made.

3- Data are not required because of the type of formulation, method of application and end-use pattern. Data are required for the registration of a non domestic (greenhouse) use.

TABLE-B: BUTOXICARBOXIME
PRODUCT-SPECIFIC DATA REQUIREMENTS: PROPOSED MANUFACTURING-USE PRODUCTS
TOXICOLOGY

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? Month and year data due.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes[1]	Each Product	Yes[2]	Til et al., 1977, GS0077022	----------
163.81-2	Acute Dermal Toxicity	Yes[1]	Each Product	Yes[2]	Huisman & Williams, 1972, GS0077010	----------
163.81-3	Acute Inhal. Toxicity	Yes[1]	Each Product	Yes[2]	Kruysse, 1973, GS0077012	----------
163.81-4	Prim. Eye Irritation	Yes[1]	Each Product	Yes[2]	Van Beek, 1977, GS0077027	----------
163.81-5	Primary Dermal Irritation	No[3]				

Data Requirements are current as of August, 1981. Refer to Guidance Package for any new Requirements after this date.

1- Testing on the manufacturing-use product is required if the proposed product is not toxicologically equivalent to the technical grade of the active ingredient.
2- Available data are on technical grade of the active ingredient.
3- Testing is not required because of low potential for exposure to end-use prouct.

TABLE-C: BUTOXYCARBOXIM
PRODUCT-SPECIFIC DATA REQUIREMENTS: END-USE PRODUCTS
PRODUCT CHEMISTRY

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)? Month and year data due.
PRODUCT CHEMISTRY						
163.61-3	Prod. Identity and Disclosure of Ingredients	Yes	Each Product[1]	Yes	Wacker Chemie, 1974, GS0077031	No[3]
163.61-4	Description of Manufacturing Process	Yes	Each Product[1]	Yes	Mueller et al., 1970, GS0077015 Wacker Chemie, 1977, GS0077038	No[3]
163.61-5	Disc. of Formation of Unint. Ingredients	Yes	Each Product[1]	Yes	Wacker Chemie, 1974, GS0077031	No[3]
163.61-6	Declaration of Ingredient Limits	Yes	Each Product[1]	Yes	Wacker Chemie, 1974, GS0077031	No[3]
163.61-7	Product Analyt. Methods and Data	Yes	Each Product[1]	Yes	Wacker Chemie, 1976, GS007738 Braunling, 1973, GS0077002	No[3]
163.61-8(7)	Physical State	Yes	End-use Product	Yes	Wacker Chemie, 1974, GS0077031	No[3]
163.61-8(8)	Density or Specific Gravity	No[2]	Technical	No		
163.61-8(10)	Vapor Pressure	No[2]	Technical	Yes	Wacker Chemie, 1974, GS0077031	No
163.61-8(11)	pH	No[2]	Technical	No		
163.61-8(12)	Storage Stab.	No[2]	Technical	Yes	Braunling, 1976, GS0077006 Braunling, 1974, GS0077005	No
163.61-8(13)	Flammability	No[2]	Technical	No		
163.61-8(14)	Oxidizing or Reducing Action	No[2]	Technical	No		
163.61-8(15)	Explosiveness	No[2]	Technical	No		
163.61-8(16)	Miscibility	No[2]	Technical	No		
163.61-8(17)	Viscosity	No[2]	Technical	No		
163.61-8(18)	Corrosion Characteristics	No[2]	Technical	No		

Data requirements are current as of August, 1981. Refer to Guidance Package for new requirements after this date.

* For Currently Registered Product.

1- Because there is no registered manufacturing-use product, information is needed on both technical grade butoxicarboxim and the registered end-use product.

2- Data are not required because of the type of formulation, method of application and use pattern. Data are required for the registration of a non-domestic (greenhouse) use.

3 These data will support the registration of only the currently registered end-use product. Applicants for the registration of new products must submit data on the proposed product.

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TABLE-C: BUTOXICARBOXIME
PRODUCT-SPECIFIC DATA REQUIREMENTS: END-USE PRODUCTS
TOXICOLOGY

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? Month and Year Data Due.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	Extract of "Pin"**	Yes	Til et al., 1977, GS0077022	No
163.81-2	Acute Dermal Toxicity	No[1]	Technical	Yes	Huisman & Williams, 1972, GS0077010	No
163.81-3	Acute Inhal. Toxicity	No[1]	Technical	Yes	Kruysse, 1973, GS0077012	No
163.81-4	Prim. Eye Irritation	Yes	Extract of "Pin"**	Yes	Van Beek, 1977, GS0077027	No
163.81-5	Primary Dermal Irritation	No[2]				

Data Requirements are current as of August, 1981. Refer to Guidance Package for any new Requirements after this date.

* For Currently Registered Product.
** Testing of extract from actual end-use product is required.

1- Testing on the end-use product is not required. Available data on the technical grade of the active ingredient will suffice.

2- Testing is not required because of the limited potential for exposure.

CHAPTER IV

PRODUCT CHEMISTRY OF BUTOXICARBOXIME

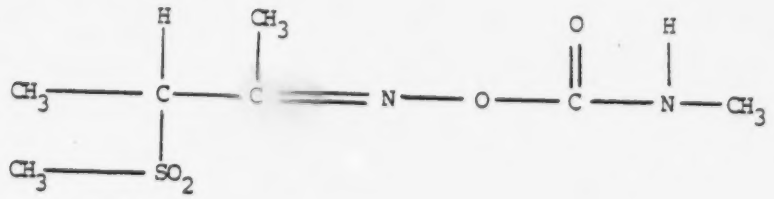
Product Chemistry: Manufacturing-use Butoxicarboxime

Product Chemistry Profile

Butoxicarboxime is the common name (accepted by the British Standards Institution and the International Organization for Standardization) for O-[(methyl-amino) carbonyl] oxime 3-(methyl-sulfonyl)-2-butanone. The American National Standards Institute (ANSI) does not recognize "butoxicarboxime" as the common name. However, "butoxicarboxime" will be used throughout this Standard in lieu of the longer chemical name.

In early phases of development, butoxicarboxime was referred to as Wac 8594OS. Other synonyms include butoxicarboxim, Co. 859, and butoxycarboxime. The Chemical Abstracts Registry Number (CAS Number) for O-[(methyl-amino) carbonyl] oxime 3-(methyl-sulfonyl)-2-butanone is 39196-18-4. The EPA Shaughnessy Number is 113001. Henley + Co. Inc. is the sole domestic distributor of the only registered product, marketed under the trade name Plant Pin® and produced by Wacker Chemie of West Germany.

The chemical formula is $C_7H_{14}N_2O_4S$, and the molecular weight is 222. The structural formula is:



Technical grade butoxicarboxime contains a minimum of 94-96% O-[(methyl-amino) carbonyl] oxime 3-(methyl-sulfonyl)-2-butanone. Butoxicarboxime is a colorless crystalline solid with a melting point of 85-89°C, and a vapor pressure of 2×10^{-6} mg Hg at 20°C (Wacker Chemie, 1974, GS0077031). Butoxicarboxime has a slightly pungent odor. Butoxicarboxime is 50% soluble in water, readily soluble in chloroform, acetone, methanol, and ethanol, and almost insoluble in petroleum and carbon tetrachloride (Wacker Chemie, 1974, GS0077031). Butoxicarboxime, formulated as an end-use product, is stable for up to 5 years (Braunling, 1976, GS0077006; Braunling, 1974, GS007705).

A detailed description of the manufacturing process for technical grade butoxicarboxime was available (Mueller et al., 1970, GS0077015). The manufacturing process cannot be described in this Standard because this information is considered to be confidential business information. The manufacturing process, as submitted by Wacker Chemie, is adequate to satisfy Agency requirements.

Wacker Chemie has also submitted a confidential statement of ingredients contained in technical grade butoxicarboxime (Wacker Chemie, 1974, GS0077031). Submitted data are adequate to satisfy Agency requirements.

An adequate analytical method for the identification and quantification of butoxicarboxime in end-use products has been submitted (Wacker Chemie, 1976, GS0077038). According to this method, a suitable amount of sample is weighed and then dissolved in chloroform. An appropriate amount of octamethyltetrasiloxane (OMS) is added to the solution, and then the NMR spectrum is determined. The amount of butoxicarboxime is quantified through calculations derived from the spectrum. Sufficient data, generated from the application of the method described above, have been provided to fulfill Agency requirements (Braunling, 1973, GS007702).

Data generated to fulfill data requirements for the physical/chemical properties of technical grade butoxicarboxime will satisfy Agency requirements for this type of data on end-use butoxicarboxime (formulated as a "pin" for insertion into soil).

Product Chemistry: End-use Formulations

Product Chemistry Profile

The sole registered end-use butoxicarboxime product is a 9.8% (by weight) "pin". A butoxicarboxime "pin" contains butoxicarboxime wedged between two 8 mm X 40 mm cardboard strips, which are glued together. The currently registered end-use product contains an intentionally added child repellant ingredient. This ingredient is added to decrease the likelihood of the accidental ingestion of fatal quantities of butoxicarboxime by young children.

Available data on the identity and quantities of inert ingredients in the currently registered end-use product are sufficiently detailed to fulfill Agency requirements. The description of the manufacturing process, provided to the Agency by Wacker Chemie (1976, GS0077038), is also adequate.

Data on the physical/chemical properties of the formulation used to make butoxicarboxime "pins" are not specifically required. Data generated on technical grade butoxicarboxime provide sufficient information.

Data are not required for Sections 163.61-8(8)-(18) because of the type of registered end-use formulation and method of application. These data would be required to support non domestic, outdoor or food uses.

CHAPTER V

ENVIRONMENTAL FATE OF BUTOXICARBOXIME

Use Pattern Profile

Butoxicarboxime is a systemic plant insecticide registered for the control of aphids and two-spotted spider mites on potted ornamental plants. Butoxicarboxime is formulated as a 9.8% cardboard "pin". The "pin" is pushed completely into the soil of a potted plant approximately one inch from the plant stem. Butoxicarboxime is released by moisture in the soil and absorbed by the roots of the plant. Following absorption, butoxicarboxime is translocated into the plant.

Environmental Fate Profile

The sole registered product containing butoxicarboxime as an active ingredient is an end-use product currently registered for indoor uses only. Although data on the physico-chemical degradation, mobility, and metabolism of butoxicarboxime are not currently required for registration, some information is available.

Wacker Chemie (Braunling 1973, GS0077003) reported to the Agency that butoxicarboxime does not hydrolyze or photodegrade under normal environmental conditions. In one study, 52.1 mg of butoxicarboxime (formulated as a "pin") was placed in the soil of a potted plant. The soil was analyzed for residues of butoxicarboxime by GLC. At 91 days, only 0.23 mg of butoxicarboxime remained (Braunling 1973, GS0077003). Submitted data suggest a half-life in soil of approximately 50-60 days.

Greenhouse testing shows that more than 90% of butoxicarboxime diffuses out of the cardboard "pins" within two days of application (Braunling 1973, GS0077003).

Exposure Profile

Butoxicarboxime is a non-volatile systemic insecticide which is not currently registered for outdoor or food uses. The Agency does not anticipate that significant exposure of either man or his environment to butoxicarboxime will occur from the use of butoxicarboxime in houseplants.

The Agency has identified the possibilities of accidental ingestion of butoxicarboxime by children, and accidental ocular exposure (through touching of exposed hands to eyes) as potential routes of exposure.

CHAPTER VI

TOXICOLOGY OF BUTOXICARBOXIME

Introduction

The first section of this chapter discusses the toxicity of butoxicarboxime as an active ingredient. The data discussed here pertain to the properties of butoxicarboxime as an active ingredient, and are relevant to an evaluation of the risks of all products containing this active ingredient. This type of data is referred to as "generic" data.

The second section of this chapter discusses the toxicity of the sole registered end-use product containing butoxicarboxime.

Wacker Chemie (the sole registrant) markets an insecticide for use on agricultural crops in countries outside the United States. The active ingredient in this insecticide is butocarboxime (3-(methylthio)-O-[(methylamino) carbonyl] oxime-2-butanone. Bu toxi carboxime, the active ingredient in Plant Pin®, is a derivative of butocarboxime. In plants and animals, butocarboxime oxidizes to butoxicarboxime. Thus, available acute and chronic testing of butocarboxime will fulfill Agency testing requirements for testing of technical grade butoxicarboxime.

Acute dermal and inhalation toxicity testing of technical grade butocarboxime or butoxicarboxime will provide sufficient data to support the registration of the currently registered end-use product. Acute oral toxicity testing and primary eye irritation testing of extracts of the currently registered end-use product is required. These data were available for review, and satisfied Agency requirements.

A. Manufacturing-use Butoxicarboxime

As discussed in chapter II, there is no currently registered manufacturing-use butoxicarboxime product. However, acute oral, dermal, and inhalation toxicity data, acute delayed neurotoxicity data, and teratogenicity data on technical grade butoxicarboxime (or technical grade butocarboxime) are required for the registration of end-use products.

Although the use pattern and method of application indicate that chronic exposure to butoxicarboxime is unlikely, a substantial quantity of both acute and long term toxicity testing of butocarboxime (and butoxicarboxime) was available for review. Presumably, these data were needed for the registration of butocarboxime abroad for use on agricultural crops.

Toxicology Profile

Acute Toxicity

Single dose oral toxicity testing of technical grade butoxicarboxime (94-96% pure) in rats and rabbits suggest moderate acute oral toxicity. The LD50 in rabbits is 275 mg/kg (Zipf, 1971, GS0077045), and the LD50 in rats is 458 mg/kg (Zipf, 1971, GS0077043). The reported acute oral LD50 values place technical grade butoxicarboxime in Category II for acute oral toxicity.

An acute dermal LD50 value of 360 mg/kg for technical grade butocarboxime in albino rabbits was established (Huismans and Williams, 1972, GS0077010). This value suggests a moderate (Category II) acute dermal toxicity.

The acute intraperitoneal toxicity of an extract of end-use butoxicarboxime was determined in albino rats (Zipf, 1971, GS0077044). The reported LD50 was 220 mg/kg body weight. Signs of toxicity included tremors and diarrhea.

In acute inhalation toxicity testing, an LC50 value of greater than 4.6 mg/L in albino rats was established for a 50% emulsifiable concentrate containing butocarboxime as the active ingredient (Kruysse, 1973, 0077012).

Eye irritation testing of technical grade butocarboxime in albino rabbits indicated that this substance is a severe irritant (Category I), inducing corneal lesions and irreversible (longer than 7 days) conjunctivitis (Huismans & Williams, 1972, GS0077010). It is thought that butocarboxime is more irritating to eyes than butoxicarboxime because of differences in water solubility, with butoxicarboxime being more water soluble and therefore more easily rinsed from the eye through the natural tearing process.

Neurotoxicity testing of technical grade butoxicarboxime in domestic hens indicated no delayed neurotoxic effects at dosages up to 367 mg/kg (Ross et al., 1977, GS0077018).

Subchronic Toxicity

The subchronic (28-day) toxicity of extracts of end-use butoxicarboxime to albino rats was evaluated in a 28-day range-finding study (Til, 1973, GS0077024). Rats were fed a preparation derived from end-use butoxicarboxime.

Diets contained 300, 1,000, qnd 3,000 ppm of the active ingredient (butoxicarboxime). The No Observable Effect Level (NOEL) of butoxicarboxime was 300 ppm for cholinesterase depression.

The subchronic (90-day) toxicity of technical grade butoxicarboxime was evaluated in a study utilizing albino rats as the test species (Sinkeldam, 1974, GS0077019). The test material (technical grade butoxicarboxime) was administered at dietary levels of 0, 100, 300, and 1,000 ppm. The No Observable Effect Level (NOEL) for technical grade butoxicarboxime was 300 ppm or 15 mg/kg body weight. A decrease in body weight and in red blood cell and brain cholinesterase levels occurred at dietary concentrations of 1,000 ppm.

Chronic Toxicity

Teratogenicity

Teratogenicity testing of technical grade butocarboxime in rats demonstrated that butocarboxime does not induce adverse effects on fetuses at maternal dietary levels up to 600 ppm on days 6-15 of gestation (Koeter, 1975, GS0077011).

3-Generation Reproduction

At 300 ppm dietary levels, technical grade butocarboxime slightly decreased(less than 10%) red blood cell cholinesterase levels, and slightly increased liver weights in female rats. A No Observable Effect Level (NOEL) of 100 ppm for this effect was established. No other adverse effects were reported (Til et al, 1977, GS0077025).

Mutagenicity

The mutagenic activity of technical grade butocarboxime was examined in the Salmonella/microsome mutagenicity test. Reported results did not indicate that butocarboxime is mutagenic (Willems, 1977, GS0077042).

Chronic Feeding/Oncogenicity

General condition, behavior, survival, growth, and histopathology were not adversely affected at any dietary level (30, 100 or 300 ppm) of technical grade butocarboxime in rats. Oncogenic potential was negative. Plasma and red blood cell cholinesterase levels were decreased at 300 ppm. The No Observable Effect Level (NOEL) reported in this study, for plasma and red blood cell cholinesterase depression was 100 ppm (Til et al, 1977, GS0077023).

B. End-use Butoxicarboxime

Acute oral toxicity testing and primary eye irritation testing of extracts of end-use butoxicarboxime are required for the registration of this particular type of formulation (butoxicarboxime impregnated between two cardboard strips). Submitted data were reviewed and found to be acceptable. Other categories of acute toxicity testing of end-use butoxicarboxime (acute dermal toxicity, acute inhalation toxicity, and primary dermal irritation) are not currently needed because exposure through these routes is not expected to be significant, and available data on technical grade butocarboxime and butoxicarboxime indicate low to moderate toxicity.

Data generated on technical grade butocarboxime or technical grade butoxicarboxime are relevant to the hazard evaluation of the end-use product.

Acute Toxicity

The acute oral LD50 of extracts from formulated butoxicarboxime (containing 9.8% butoxicarboxime) is greater than 5 gms/kg body weight in rats (Til et al., 1977, GS0077022). This places the currently registered end-use product in Category IV for acute oral toxicity.

Primary eye irritation testing of extracts from formulated butoxicarboxime (containing 9.8% butoxicarboxime) indicates moderate to low (Category II) irritability in rabbits (Van Beek, 1977, GS0077027).

CHAPTER VII

RESIDUE CHEMISTRY

Butoxicarboxime is not currently registered for agricultural uses.

For future registration of a butoxicarboxime product for use on a food or feed crop, the Agency must be provided with a petition for tolerance, a full range of data including a validated method for analysis of residues in or on the raw agricultural commodity, data on metabolism in plants and animals (when appropriate), and residue data reflecting the proposed use of butoxicarboxime on the crop.

CHAPTER VIII

ECOLOGICAL EFFECTS OF BUTOXICARBOXIME

Butoxicarboxime is not currently registered for outdoor uses.

Although data on avian and aquatic toxicity are not currently required for the registration of an indoor use product, some information is available. Wacker Chemie (Mann, 1974, GS0077013) reported to the Agency that the LC50 for rainbow trout is 38 mg/L for technical grade butocarboxime, indicating that technical grade butocarboxime is only slightly toxic to rainbow trout. The LC50 of butocarboxime to Idus idus melantotus was also reported in this study. The reported LC50 was 56 mg/L.

Butoxicarboxime was tested for its toxicity to guppies. The LC50 was determined to be 70 mg/L (Wacker Chemie, 1972, GS0077029). The LC50 of butocarboxime in Japanese quail was determined to be 1180 ppm (with 95% confidence limits of 1009 ppm and 1381 ppm) (Til, 1974, GS0077026). This indicates that technical grade butocarboxime is only slightly toxic to Japanese quail.

For the registration of an outdoor use product, the data discussed above must be reviewed and a hazard assessment must be completed (if the data are determined to satisfy Agency requirements).

IX. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

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of the Data Base Supporting
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